FORM PTO-1390
(Rev 10-9-94)

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office
Docket No. Griffith

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. § 371

09/202035

U.S. APPLICATION NO. (If known, see 37 C.F.R. § 1.5):

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/AU97/00351	June 4, 1997	June 5, 1996

TITLE OF INVENTION: **VIRAL PEPTIDES WITH STRUCTURAL HOMOLOGY TO PROTEIN G OF RESPIRATORY SYNCYTIAL VIRUS**

APPLICANT(S) FOR DO/EO/US: Jeffrey John GORMAN

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. § 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. § 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. § 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. § 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. § 371(c)(2))
   a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☐ A translation of the International Application into English (35 U.S.C. § 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. § 371(c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. § 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. § 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. § 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 C.F.R. §§ 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. §§ 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information: return receipt postcard, substitue Figure 12.

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

Express Mail Label No.: EL 130 238 848 US Date of Deposit: December 4, 1998

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: Assistant Commissioner for Patents, Box Patent Application, Washington, D.C. 20231.

Signature ALAN IGLEHART
Printed name

U.S. APPLICATION NO. (If known, see 37 C.F.R. §1.5)	INTERNATIONAL APPLICATION NO. PCT/AU97/00351	DOCKET NUMBER: Griffith

17. ☒ The following fees are submitted:

BASIC NATIONAL FEE (37 C.F.R. §§ 1.492(a)(1)-(5)):

Search Report has been prepared by the EPO or JPO $840.00

International preliminary examination fee paid to (USPTO (37 C.F.R. § 1.482)..... $670.00

No international preliminary examination fee paid to USPTO (37 C.F.R. § 1.482) but international search fee paid to USPTO (37 C.F.R. § 1.445(a)(2)) $760.00

Neither international preliminary examination fee (37 C.F.R. § 1.482) nor international search fee (37 C.F.R. § 1.445(a)(2)) paid to USPTO $970.00

International preliminary examination fee paid to USPTO (37 C.F.R. § 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4)..... $96.00

CALCULATIONS PTO USE ONLY

			ENTER APPROPRIATE BASIC FEE AMOUNT =	$970.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 C.F.R. § 1.492(e)).				$130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	33 - 20 =	13	x $18.00	$234.00	
Independent claims	2 - 3 =	0	x $78.00	$0.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $260.00	$0.00	
			TOTAL OF ABOVE CALCULATIONS =	$1334.00	
Reduction by ½ for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 C.F.R. §§ 1.9, 1.27, 1.28)				$0.00	
			SUBTOTAL =	$1334.00	
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 C.F.R. § 1.492(f)).			+	$0.00	
			TOTAL NATIONAL FEE =	$1334.00	
Fee for recording the enclosed assignment (37 C.F.R. § 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. §§ 3.28, 3.31). **$40.00 per property**			+	$0.00	
			TOTAL FEES ENCLOSED =	$1334.00	
				Amount to be refunded:	**$**
				charged:	**$**

a. ☒ A check in the amount of **$1334.00** to cover the above fees is enclosed.

b. ☐ Please charge my **Deposit Account No. 03-1952** in the amount of $ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Assistant Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to **Deposit Account No. 03-1952**.

NOTE: Where an appropriate time limit under 37 C.F.R. § 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. § 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Gladys H. Monroy
Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, California 94304-1018

Gladys H. Monroy
SIGNATURE

Gladys H. Monroy
Registration No. 32,430

PATENT
Docket No. Griffith

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

Express Mail Label No.: EL 130 238 848 US Date of Deposit: December 4, 1998

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: Assistant Commissioner for Patents, Box Patent Application, Washington, D.C. 20231.

Alan Iglehart
Signature

ALAN IGLEHART
Printed name

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Jeffrey John GORMAN

Serial No.: To Be Assigned

Filing Date: Herewith

For: VIRAL PEPTIDES WITH STRUCTURAL HOMOLOGY TO PROTEIN G OF RESPIRATORY SYNCYTIAL VIRUS

Examiner: To Be Assigned

Group Art Unit: To Be Assigned

PRELIMINARY AMENDMENT

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Prior to examination of the above-captioned application, please enter the following amendments and remarks.

Amendment

In the specification

Page 2, line 33, delete "generus" and insert --genus--.
Page 4, line 25, delete "immunogenecity" and insert --immunogenicity--.
Page 7, line 27, delete fluorescien-labeled" and insert --fluoroscein-labelled--.
Page 36, line 17, delete "in".
Page 37, line 7, delete "pepdtide" and insert --peptide--.
Page 37, line 19, delete "Ac149-197" and insert --Ac149-177--.

In the claims

1. (Amended) A compound having structural homology to a contiguous sequence of amino acids within the sequence representing residues 149-1[9]77 of the G protein of respiratory syncytial virus, in which

a) no oligosaccharide is linked to potential serine, threonine or asparagine attachment sites;

b) four cysteine residues are involved in disulphide linkages; and

c) the pattern of disulphide linkage is Cys 173 linked to Cys 186, and Cys 176 linked to Cys 182,

and in which said compound possesses a biological activity of respiratory syncytial virus G protein.

2. (Reiterated) A compound according to claim 1 in which the virus is selected from the group consisting of human RSV subtype A, human RSV subtype B, bovine RSV, and mutants and variants thereof.

3. (Amended) A compound according to Claim 1 [or Claim 2] in which the compound is a peptide corresponding to amino acids 158 to 196 of the RSV G protein.

4. (Amended) A compound according to [any one of] Claim[s] 1 [to 3] in which the peptide corresponds to amino acids 165 to 187 of the RSV G protein.

5. (Amended) A compound according to [any one of] Claim[s] 1 [to 4] in which the compound is a peptide having one of the following amino acid sequences:

SEQ ID NO 1	K Q R Q N K P P S K P N N D F H F E V F N F V P C S I C S N N P T C W A I C K R I P N K K P G K K
SEQ ID NO 2	N
SEQ ID NO 3	R
SEQ ID NO 4	H
SEQ ID NO 5	N
SEQ ID NO 6	N
SEQ ID NO 7	N
SEQ ID NO 8	R
SEQ ID NO 9	S S K N K K D Y G Q L K S T S N K
SEQ ID NO 10	S S K N K K D Y G Q L K S T S N K
SEQ ID NO 11	P P K N K K D Y G Q L K S T S N K
SEQ ID NO 12	P P K N K K D Y G Q L K S T S N K
SEQ ID NO 13	P P K N K K D Y G Q L K S T S SN K
SEQ ID NO 14	P P K N K K D Y G QL K S T S N K
SEQ ID NO 15	S S K N K K D Y G QL K S T S N K
SEQ ID NO 16	N P S G S I E N HQ D HN N Q T LP Y TE G L A L S L HIET E RA SR A
SEQ ID NO 17	P T R
SEQ ID NO 18	S R T

6. (Reiterated) A compound having structural homology to a contiguous sequence of amino acids within the sequence representing residues 149-197 of the G protein of RSV, in which at least one of cysteines 173, 176, 182 and 186 is absent or blocked, and in which said compound is not glycosylated, and has the ability to inhibit infectivity of RSV.

7. (Amended) A compound according to [any one of Claims 1 to 6 in which one or more amino acids is replaced by its corresponding D-amino acids] Claim 6, selected from the group consisting of :

acetyl-KQRQNKPPSKPNNDFHFEVFNFVPCSICSNNPTCWAICKRIPNKKPGKKAmide

acetyl-KQRQNKPPSKPNNDFHFEVFNFVPCGICGAmide

fluoresceinisothiocarbamy1β-

alany1KQRQNKPPSKPNNDFHFEVFNFVPCSICSNNPTCWAICKRIPNKKPGKKAmide

fluoresceinisothiocarbamy1β-alany1FHFEVFNFVPCSICSNNPTCWAIC

KRIPNKKPGKKAmide

benzoylbenzyl-KQRQNKPPSKPNNDFHFEVFNFVPCSICSNNPTCWAICKRIPNKKPGKK

Amide

biotinyl-KQRQNKPPSKPNNDFHFEVFNFVPCSICSNNPTCWAICRIPNKKPGKKAmide

acetyl-FHFEVFNFVPCSICSNNPTCWAICKRIPNKKPGKKAmide,

in which the cysteine residues are derivatised with acetamidomethyl.

8. (Reiterated) A compound according to any one of Claims 1 to 6 which is a peptidomimetic compound.

9. (Amended) A compound according to any one of Claims 1 to [6] 7 in which one or more [individual] amino acids is replaced by [an analogous structure] its corresponding D-amino acid.

10. (Amended) A [diagnostic composition comprising a] compound according to any one of claims 1 to [10 together with an acceptable carrier] 7 in which one or more individual amino acids is replaced by an analogous structure.

11. (Amended) A [pharmaceutical composition comprising a] compound [according to any one of] selected from the group consisting of the compounds of Claims 1 to [10 together with a pharmaceutically acceptable carrier] 7, labelled with a detectable marker.

12. (Amended) [An antibody directed against a] A compound according to [any one of Claims 1 to 10] Claim 11, in which the detectable marker is a radioactive label.

13. (Amended) [An antibody] A compound according to claim [12] 11, in which [is a protective antibody] the detectable marker is a fluorescent, chemiluminescent or enzymic marker.

14. (Amended)A diagnostic composition comprising [an antibody according to Claim 12 or Claim 13] a compound selected from the group consisting of the compounds of Claims 1 to 10 together with an acceptable carrier.

15. (Amended) A pharmaceutical composition [according to any one of] comprising a compound selected from the group consisting of the compounds of Claims [10 to 12 or 13 in which the virus is human RSV] 1 to 10 together with a pharmaceutically acceptable carrier.

16. (Amended) [A method of prevention or treatment of *Pneumovirus* infection comprising the step of administering an effective amount of a compound according to any one of] An antibody directed against a compound selected from the group consisting of the compounds of Claims 1 to 10 [to a mammal in need of such treatment].

17. (Amended) [A method of diagnosis of *Pneumovirus* infection comprising exposing a biological fluid or sample from a mammal suspected of being infected with said virus to a compound according to any one of Claims 1 to 10, and measuring the interaction between the compound and said fluid or sample] An antibody according to Claim 16 which is a protective antibody.

18. (Amended) A [method of immunisation against *Pneumovirus* infection,] composition comprising [the step of immunising a mammal at risk of such infection with an immunising-effective dose of according to any one of Claims 1 to 10, said compound being immunogenic and having the ability to elicit protective] antibody selected from the group of the antibodies of Claim 16 and Claim 17.

19. (New) A composition according to any one of Claim 14 in which the virus is human RSV.

20. (New) A composition according to any one of Claim 15 in which the virus is human RSV.

21. (New) A composition according to any one of Claim 16 in which the virus is human RSV.

22. (New) A method of prevention or treatment of *Pneumovirus* infection comprising the step of administering an effective amount of a compound selected from the group consisting of the compounds of Claims 1 to 10 to a mammal in need of such treatment.

23. (New) A method of diagnosis of *Pneumovirus* infection, comprising exposing a biological fluid or sample from a mammal suspected of being infected with said virus to a compound selected from the group consisting of the compounds of Claims 1 to 10, and measuring the interaction between the compound and said fluid or sample.

24. (New) A method of immunisation against *Pneumovirus* infection, comprising the step of immunising a mammal at risk of such infection with an immunising-effective dose of a compound selected from the group consisting of the compounds of Claims 1 to 10, said compound being immunogenic and having the ability to elicit protective antibody.

25. (New) A method of identification of a cell surface receptor for respiratory syncytial virus G protein, comprising the step of detection of binding of a compound selected from the group consisting of the compounds of Claims 11 to 13 to a cell surface protein.

26. (New) A method according to Claim 24, in which the cell is susceptible to infection by respiratory syncytial virus.

27. (New) A method according to Claim 25, in which the cell is susceptible to infection by respiratory syncytial virus.

28. (New) A method according to Claim 25, in which the cell is a HEp-2 cell.

29. (New) A method according to Claim 25, in which the method comprises the step of photoaffinity labelling of the receptor with a benzoylbenzyl derivative of the compound.

30. (New) A method according to Claim 25, in which the method comprises the step of labelling of the receptor with a fluorescent derivative of the compound.

31. (New) A method according to Claim 25, in which the method comprises the steps of binding a biotinylated derivative of the compound to a receptor, and binding of avidin to the derivative.

32. (New) A method according to Claim 25, in which the method comprises the step of using an antibody according to Claim 16 to detect the binding of the compound.

33. (New) A method according to Claim 25, in which the compound is multiply derivatised, thereby to achieve combined cross-linking, detection and identification of a receptor.

In the Drawings

Please enter substitute Figure 12.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. Griffith. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: December 4, 1998

By: Gladys H. Monroy

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PCT/AU97/00351

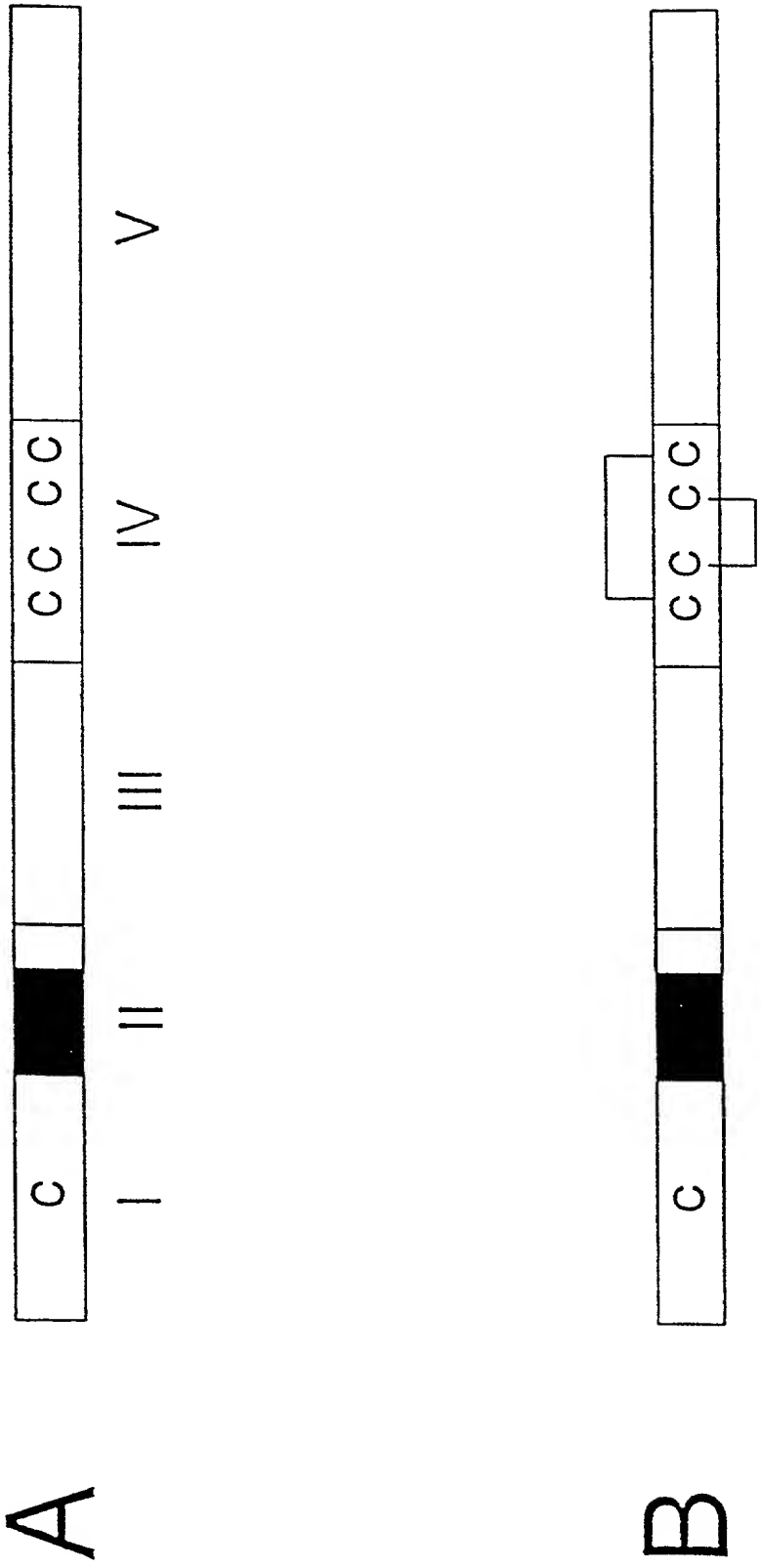


FIGURE 1

```
      150        160        170        180        190    195
      |          |          |          |          |
1  KQRQNKPPSKPNNDFHFEVFNFVPCSICSNNPTCWAICKRIPNKKPGKK   A2
2  --------N----------------------------------------   Long A
3  ------------------------------------------------R   A 642
4  --H----------------------------------------------   A 6614
5  --------N----------------------------------------   A 6256
6  --------N----------------------------------------   A 6190
7  --------N----------------------------------------   A 5857
8  ------------------------------------------------R   A 1734
9  -S-SKN--K--KD-Y-------------G--QL-KS---T--SN--K--   B 18537
10 -S-SKN--K--KD-Y-------------G--QL-KS---T--SN--K--   B 8/60
11 -P-PKN--K--KD-Y-------------G--QL-KS---T--SN--K--   B 1355
12 -P-LKN--K--KD-Y-------------G--QL-KS---T--SN--K--   B 15291*
13 -P-LKN--K--KD-Y-------------G--QL-KS---T-SSN--K--   B 10010*
14 -P-LKN--K--KD-Y-------------G--QL-KS---T--SN--K--   B 4843
15 -S-SKN--K--KD-Y-------------G--QL-KS---T--SN--K--   B 9320
16 NPSGSI--ENHQDHNN-QTLPY----T-EG-LA-LSL-HIETERA-SRA   Bovine
17 ---------------------P----T------R---------------   AR10c/1
18 -------------------S-----------------R--T--------   AR10c/10
```

FIGURE 2

* Isolates from the same child with an interval of one year between isolations.

Isolates of the human A variants R10c/1 and R10c/10 were generated by propagation of the Long A strain in the presence of a monoclonal antibody directed at the cysteine containing constant region on the G protein.

FIGURE 2 (cont.)

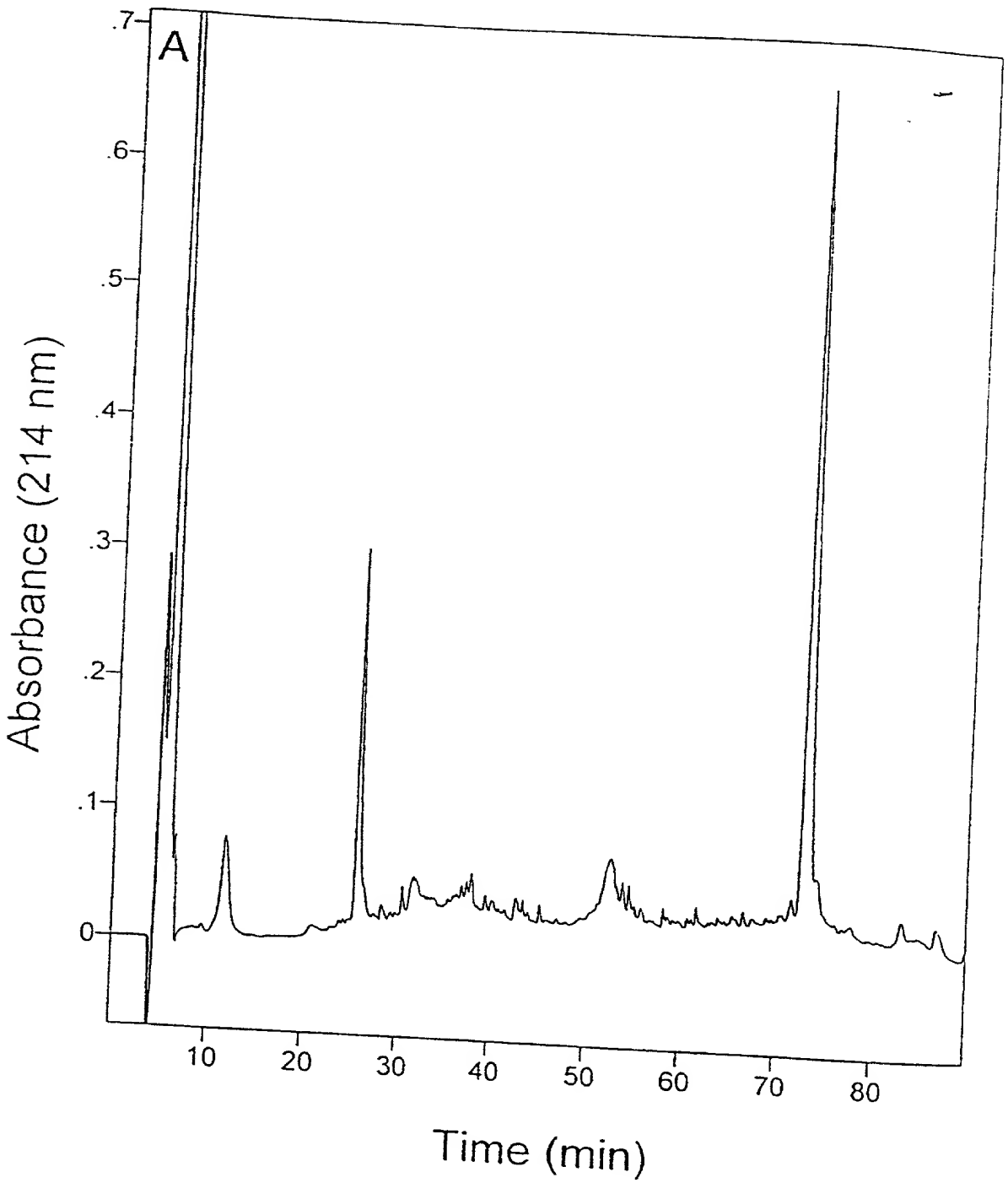
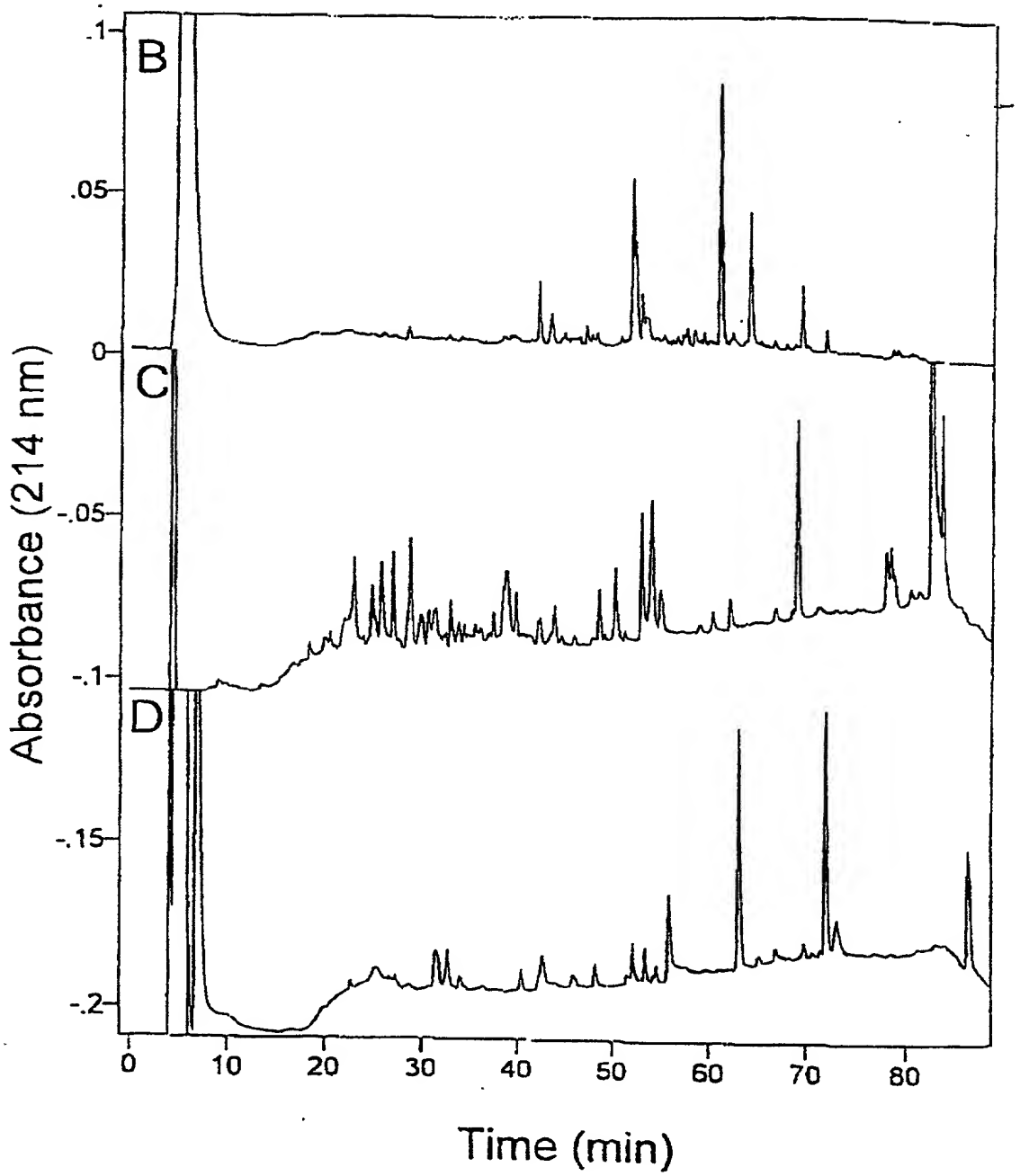


FIGURE 3A



FIGURES 3B to 3D

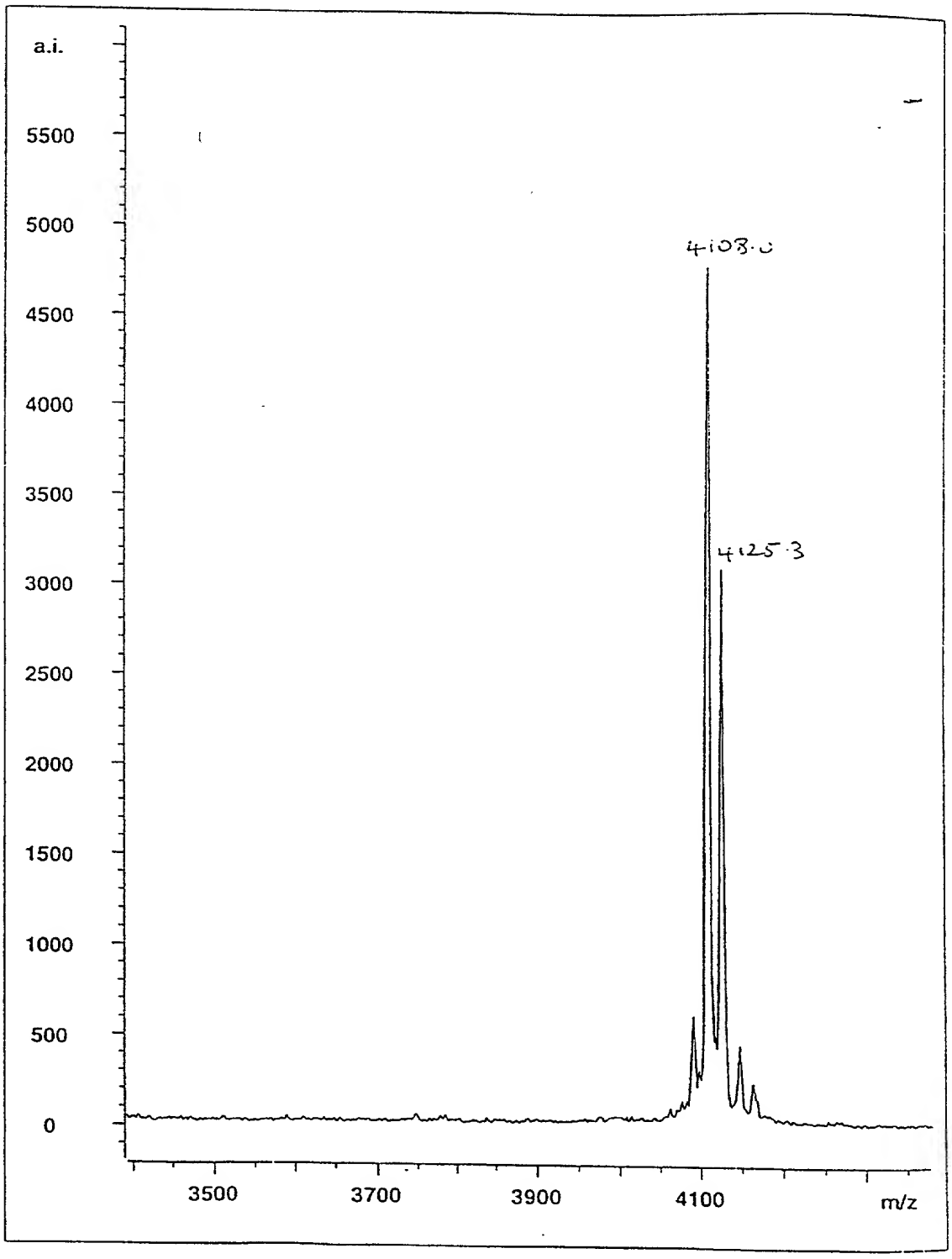

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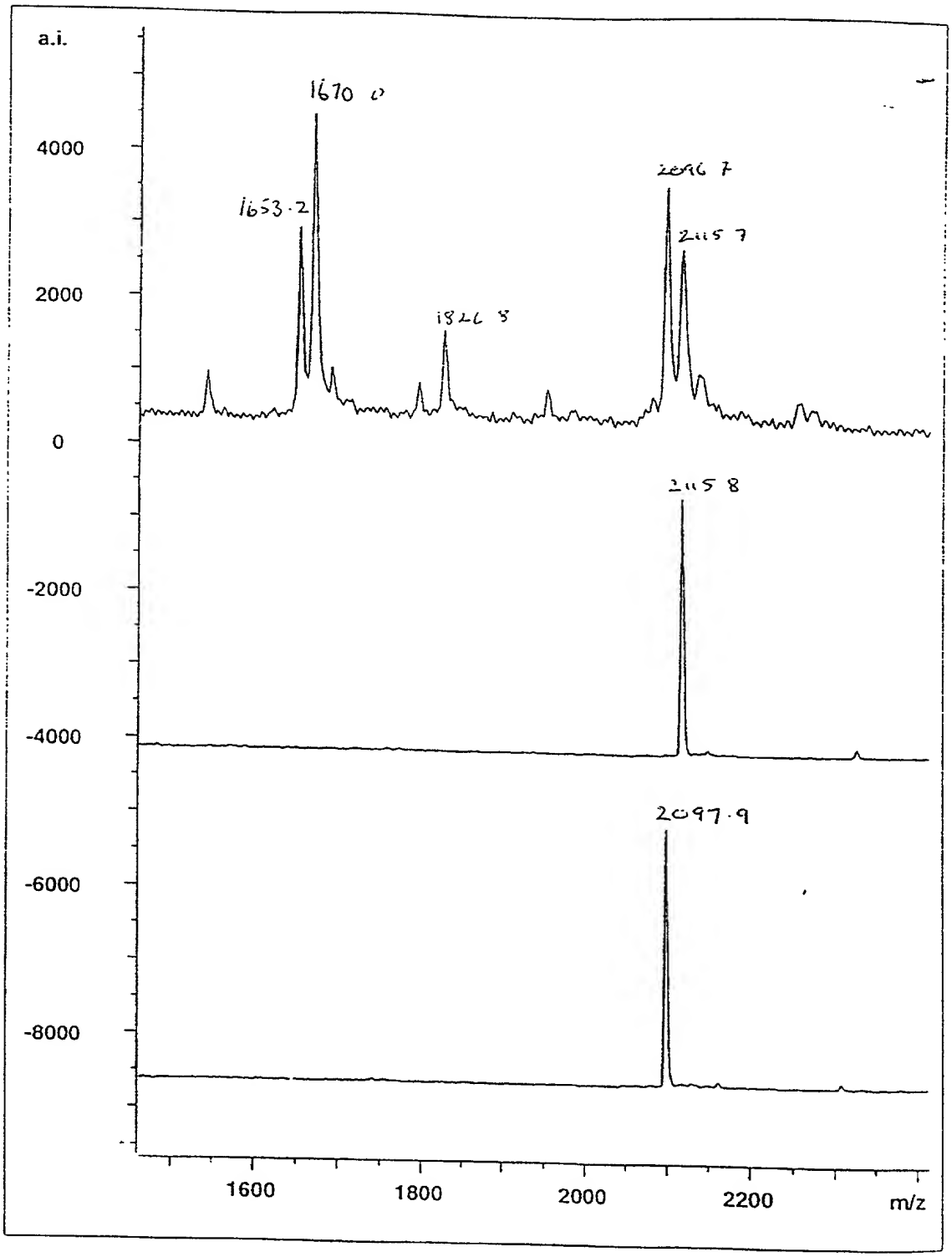
FIGURE 4A



FIGURES 4B TO 4D

FIGURE 5

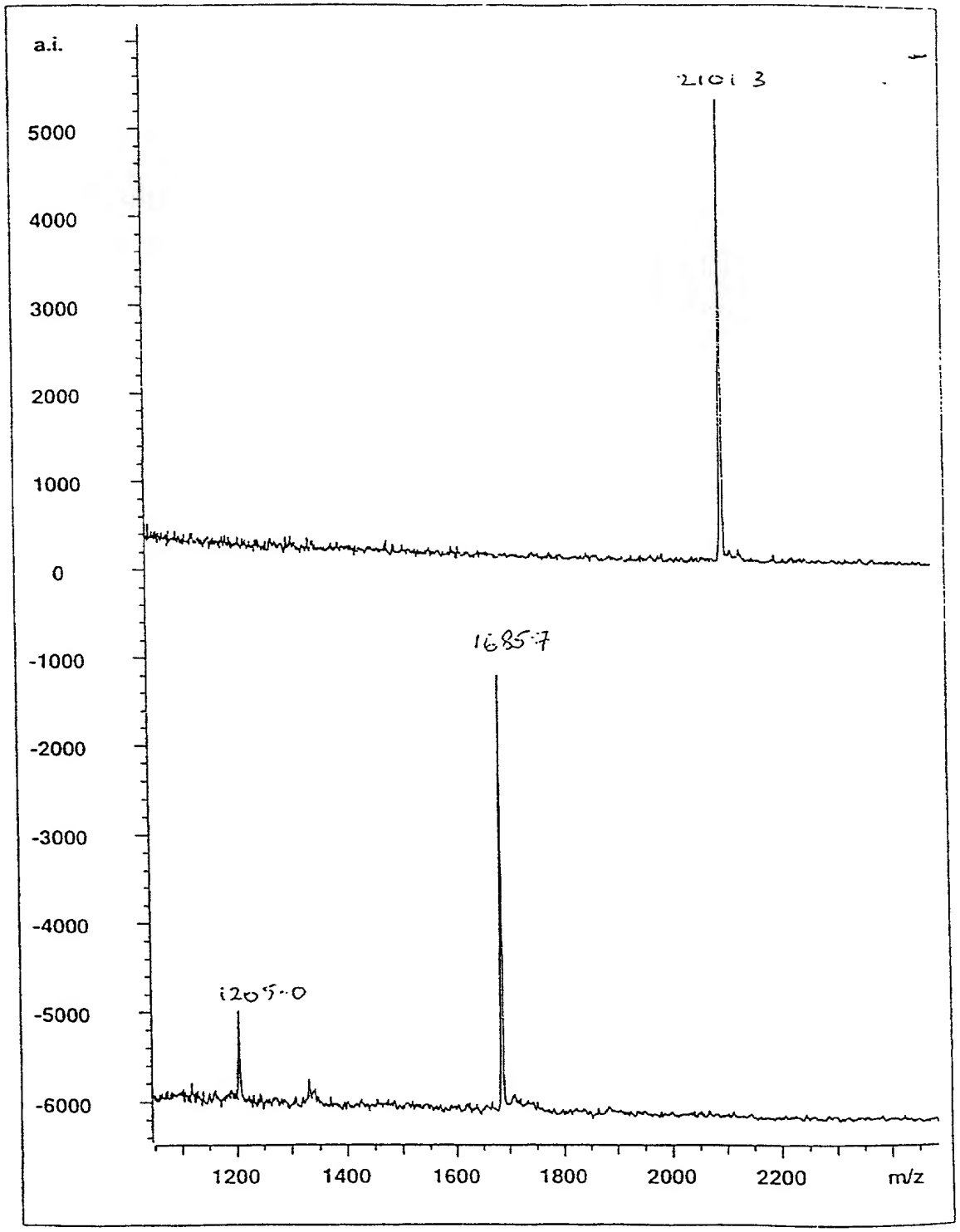

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FIGURE 6

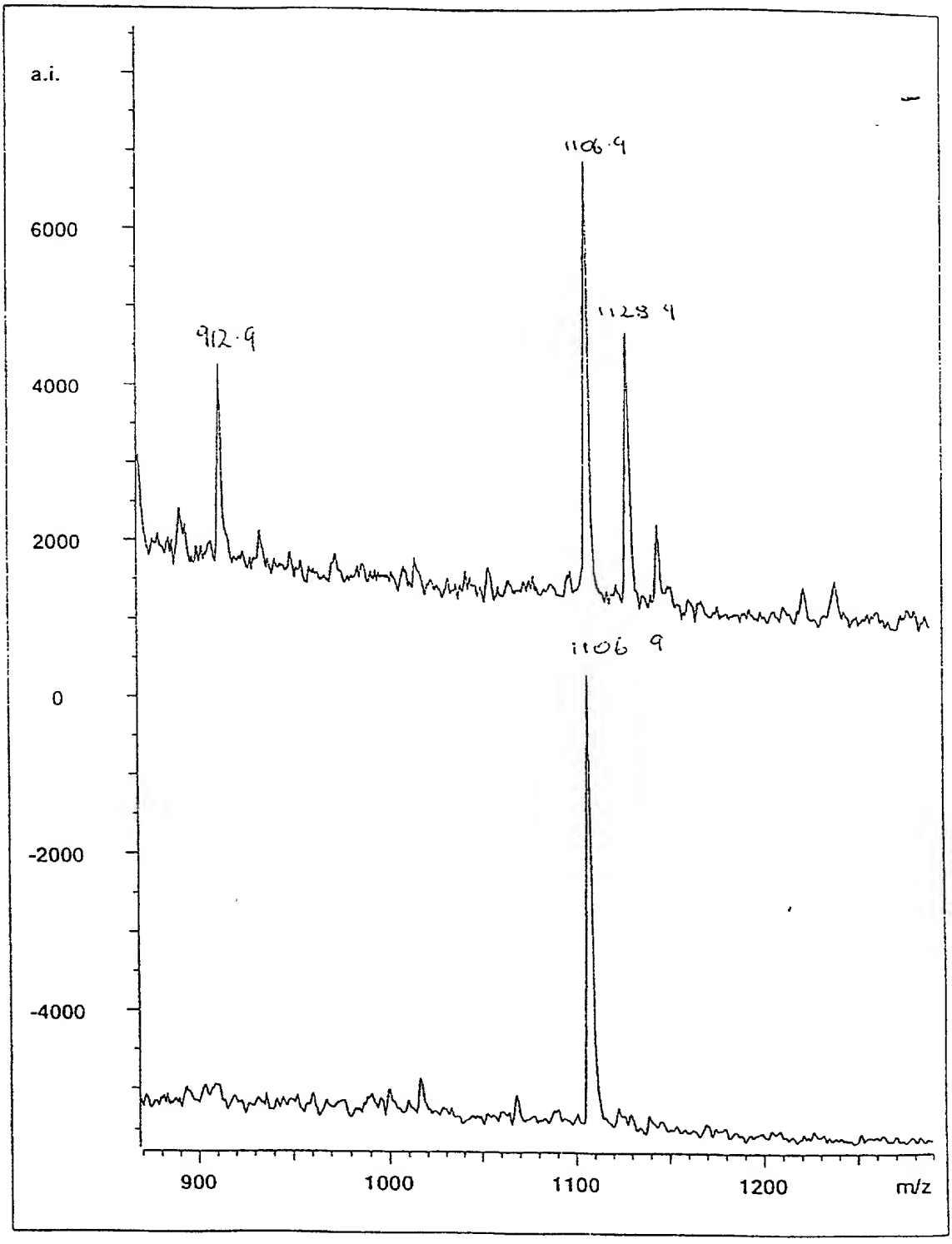
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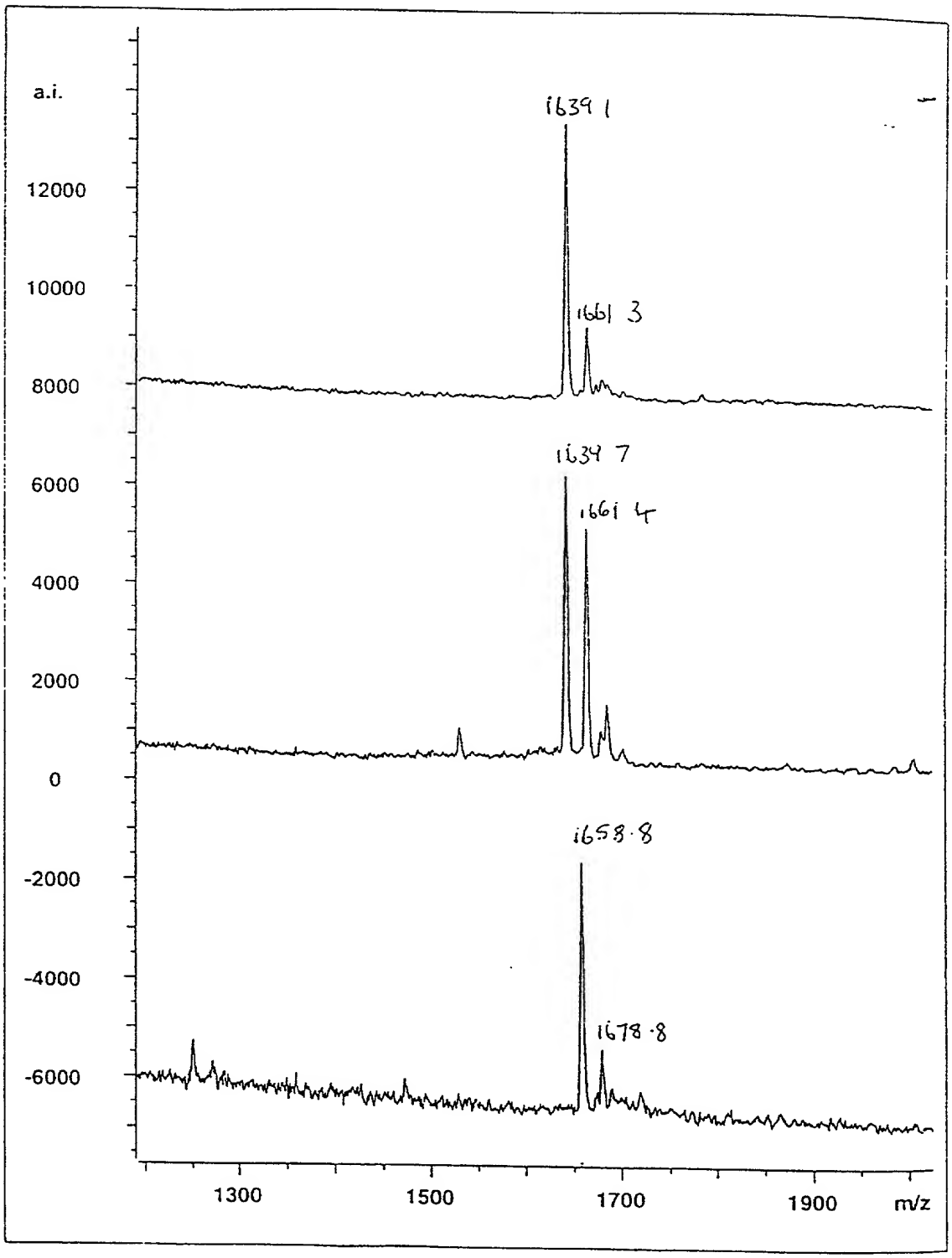
FIGURE 7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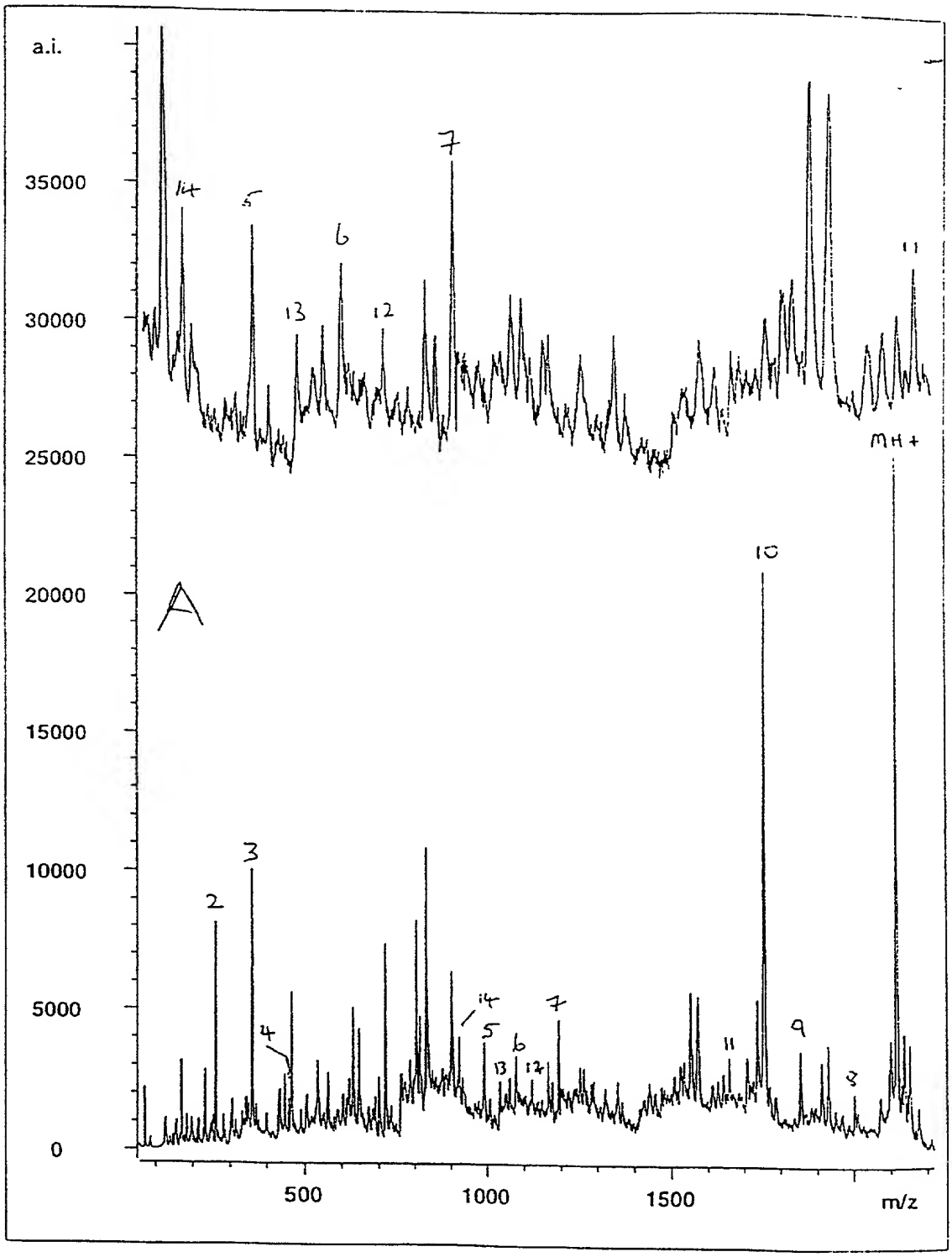
1700
1900
m/z

FIGURE 8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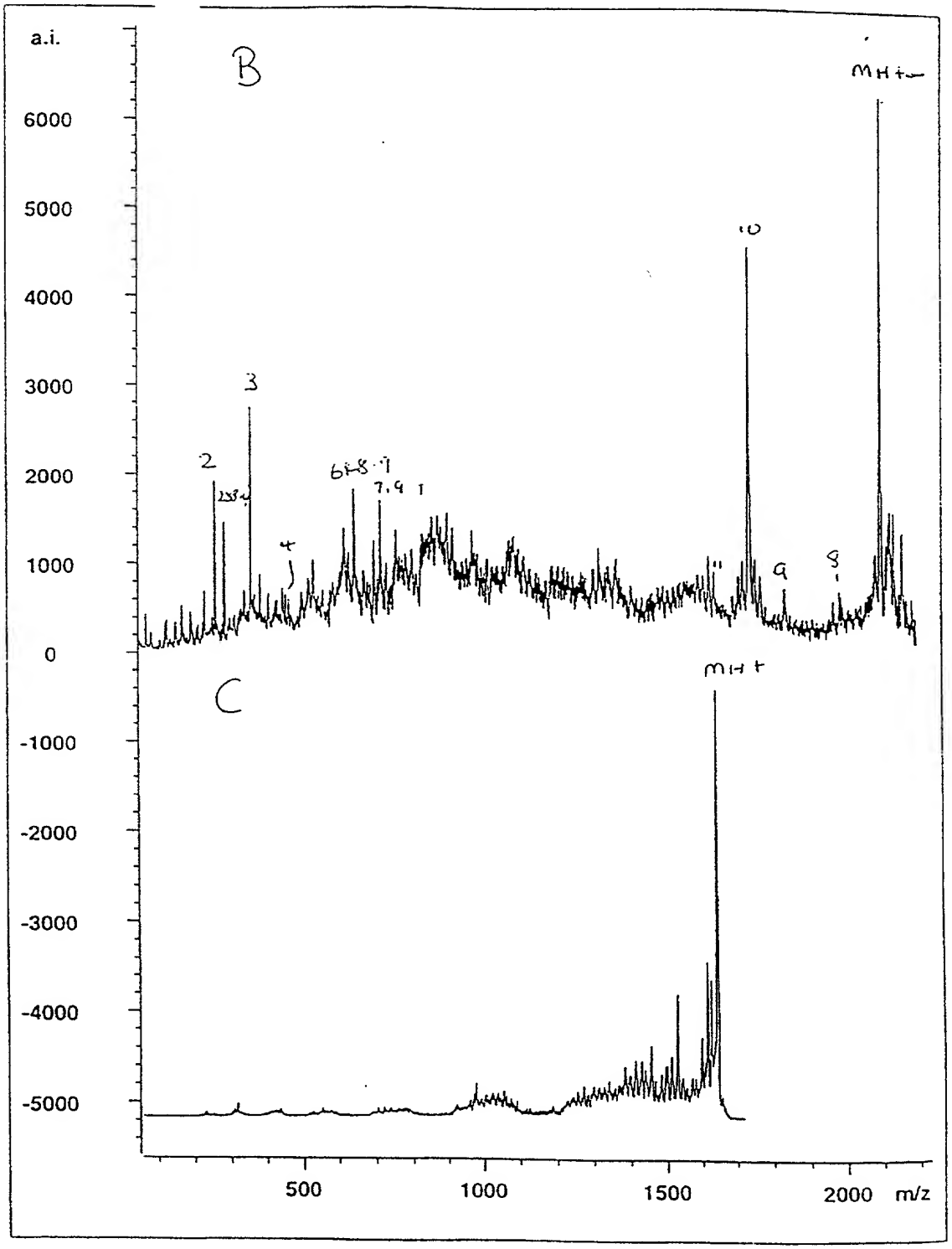
6
7
13
12
11
10
2
3
4
9
8

FIGURE 9A



FIGURES 9B & 9C

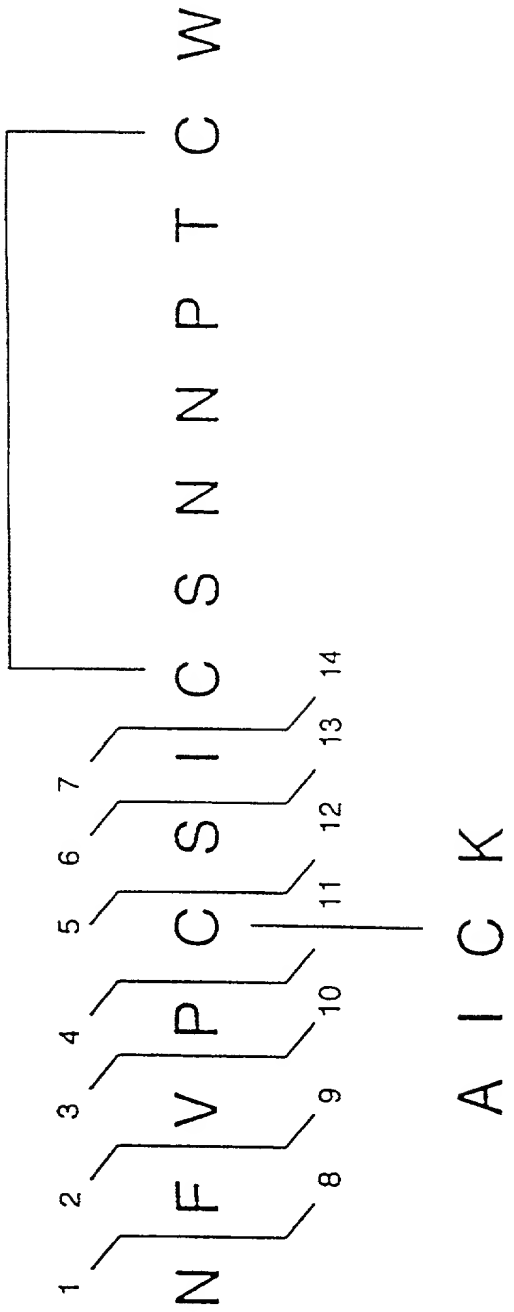
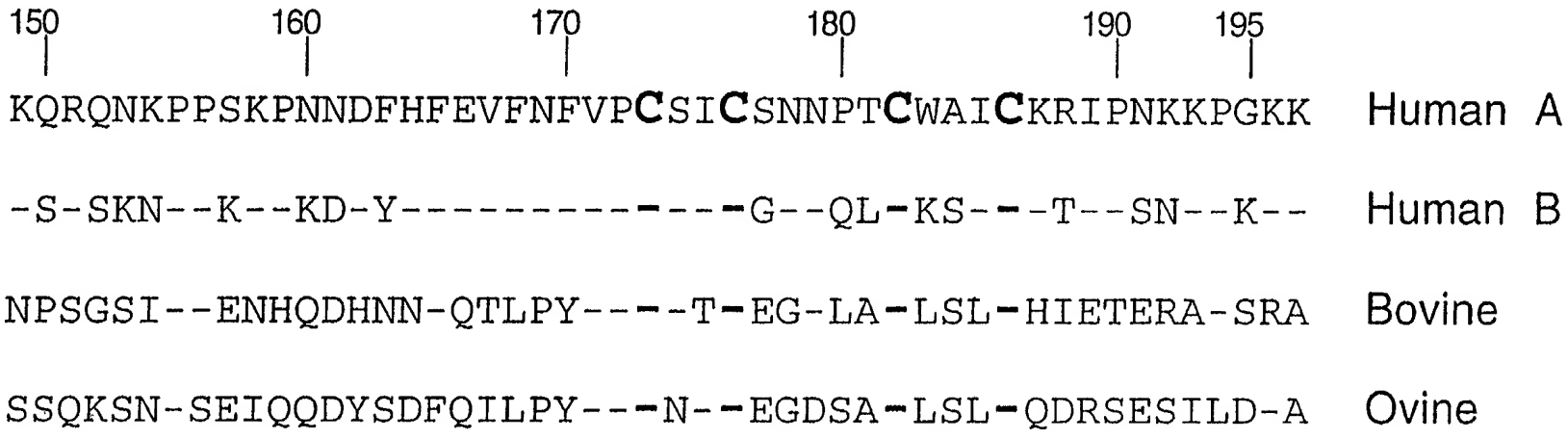


FIGURE 10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160
170
180
190
195
KQRQNKPPSKPNNDFHFEVFNFVPCSICSNNPTCWAICKRIPNKKPGKK Human A
-S-SKN--K--KD-Y----------G--QL-KS--T--SN--K-- Human B
NPSGSI--ENHQDHNN-QTLPY----T-EG-LA-LSL-HIETERA-SRA Bovine
SSQKSN-SEIQQDYSDFQILPY---N--EGDSA-LSL-QDRSESILD-A Ovine

FIGURE 11

```
        150         160         170         180         190   195
         |           |           |           |           |     |
1    AcKQRQNKPPSKPNNDFHFEVFNFVPCSICSNNPTCWAICKRIPNKKPGKKAmide
2    AcKQRQNKPPSKPNNDFHFEVFNFVPCSICSNNPTCWAICKRIPAmide
3                   AcFHFEVFNFVPCSICSNNPTCWAICKRIPNKKPGKKAmide
4    AcKQRQNKPPSKPNNDFHFEVFNFVPCSICSAmide
5  fitcKQRQNKPPSKPNNDFHFEVFNFVPCSICSNNPTCWAICKRIPNKKPGKKAmide
6                 fitcFHFEVFNFVPCSICSNNPTCWAICKRIPNKKPGKKAmide
7    bbKQRQNKPPSKPNNDFHFEVFNFVPCSICSNNPTCWAICKRIPNKKPGKKAmide
8  biotKQRQNKPPSKPNNDFHFEVFNFVPCSICSNNPTCWAICKRIPNKKPGKKAmide
9  fitcVTRQRRARNGASRS
```

FIGURE 12

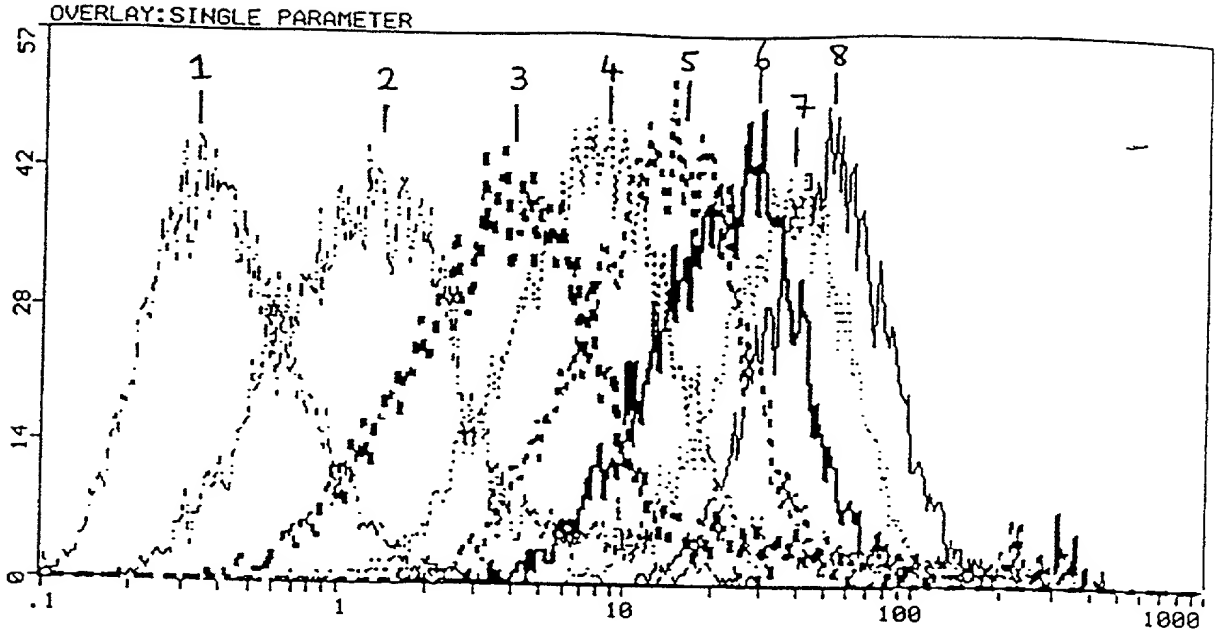

FIGURE 13

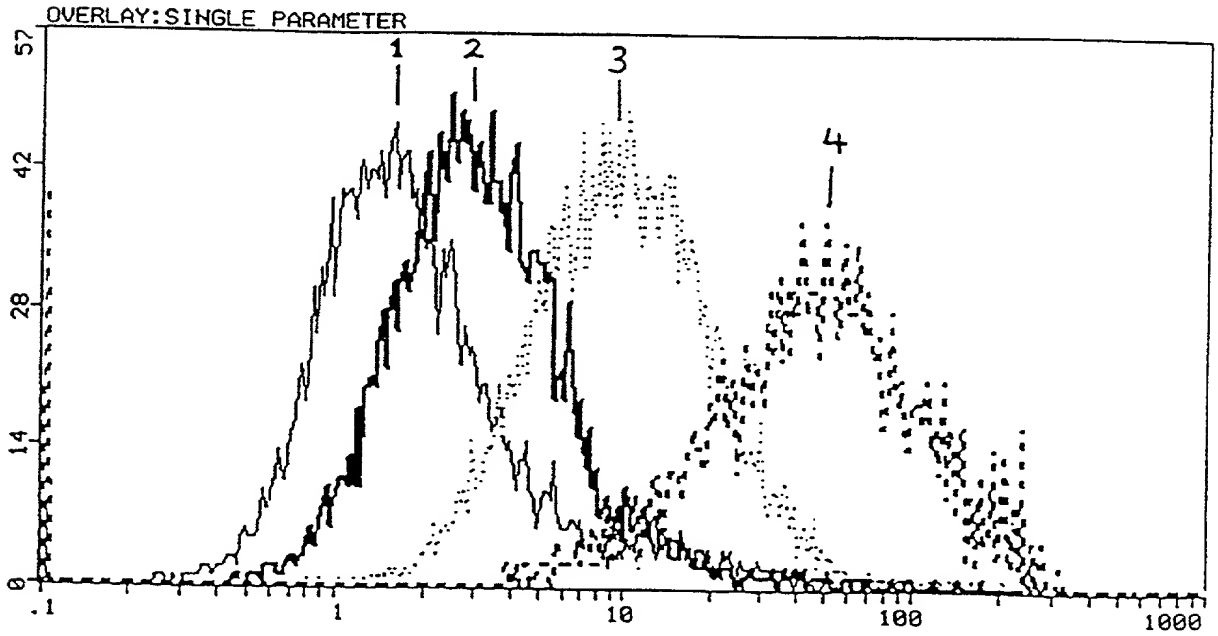

FIGURE 14

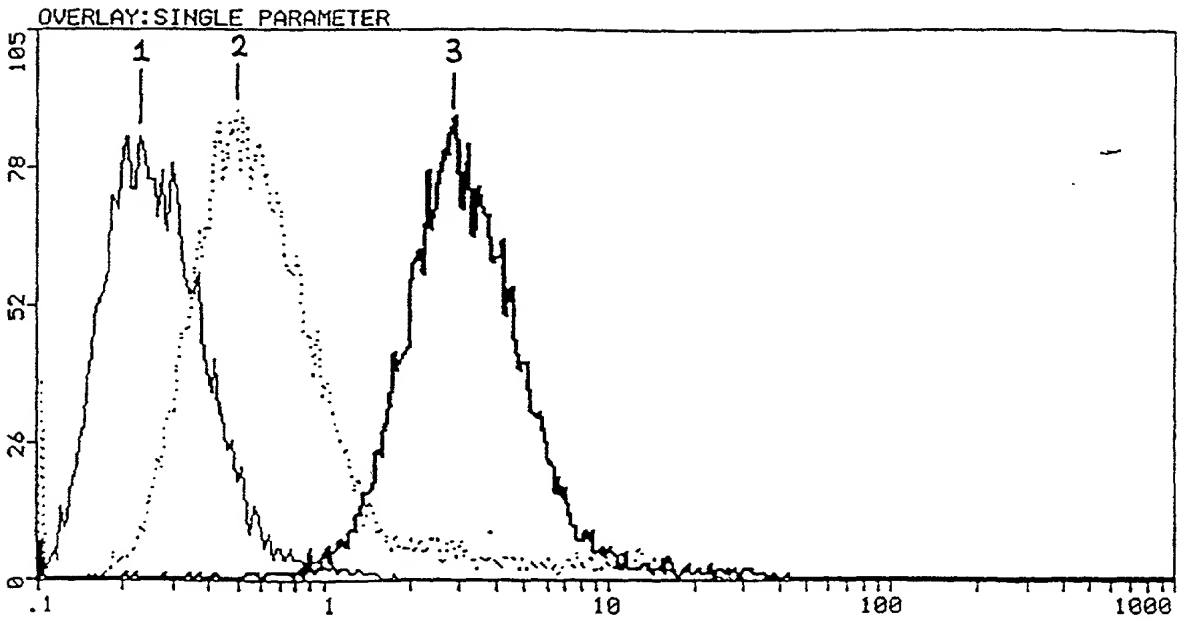

FIGURE 15

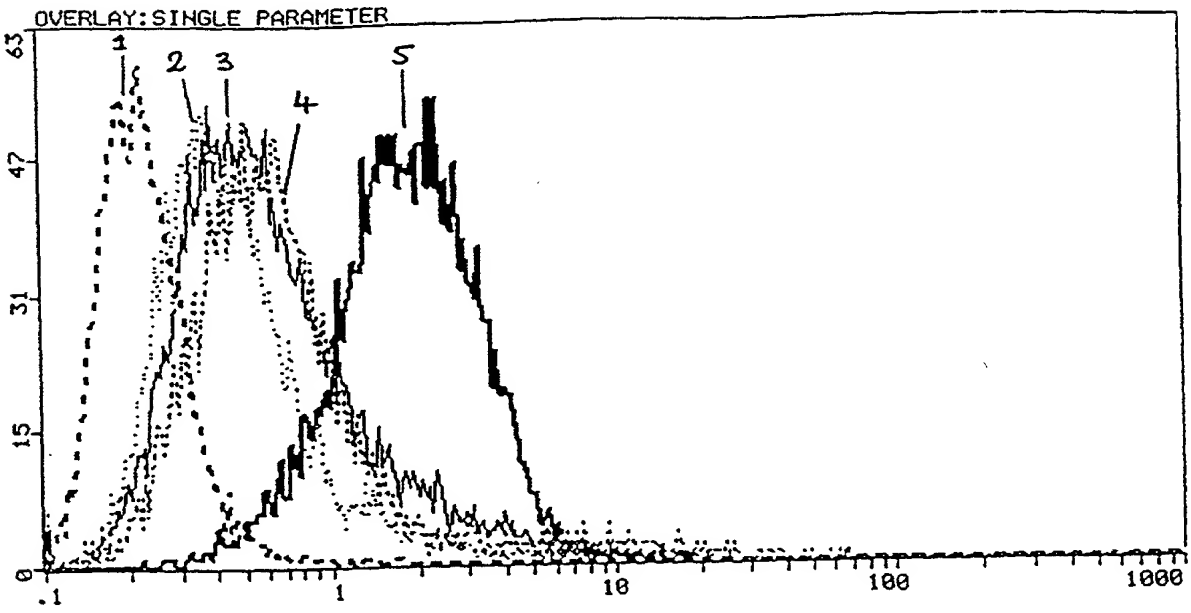

FIGURE 16

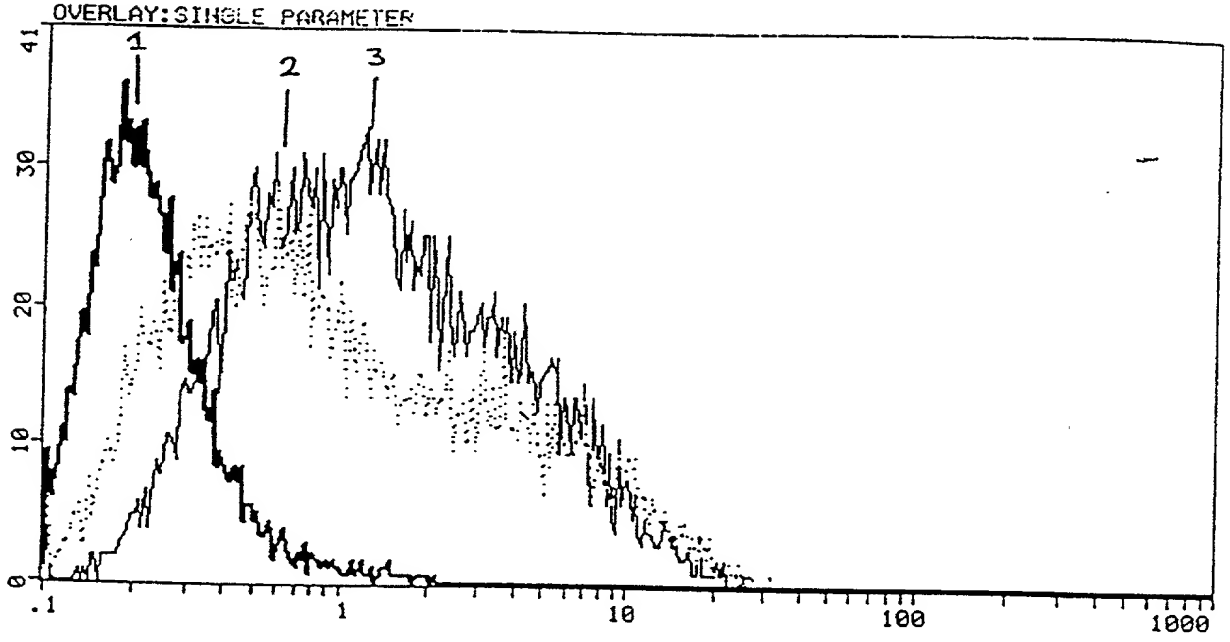

FIGURE 17

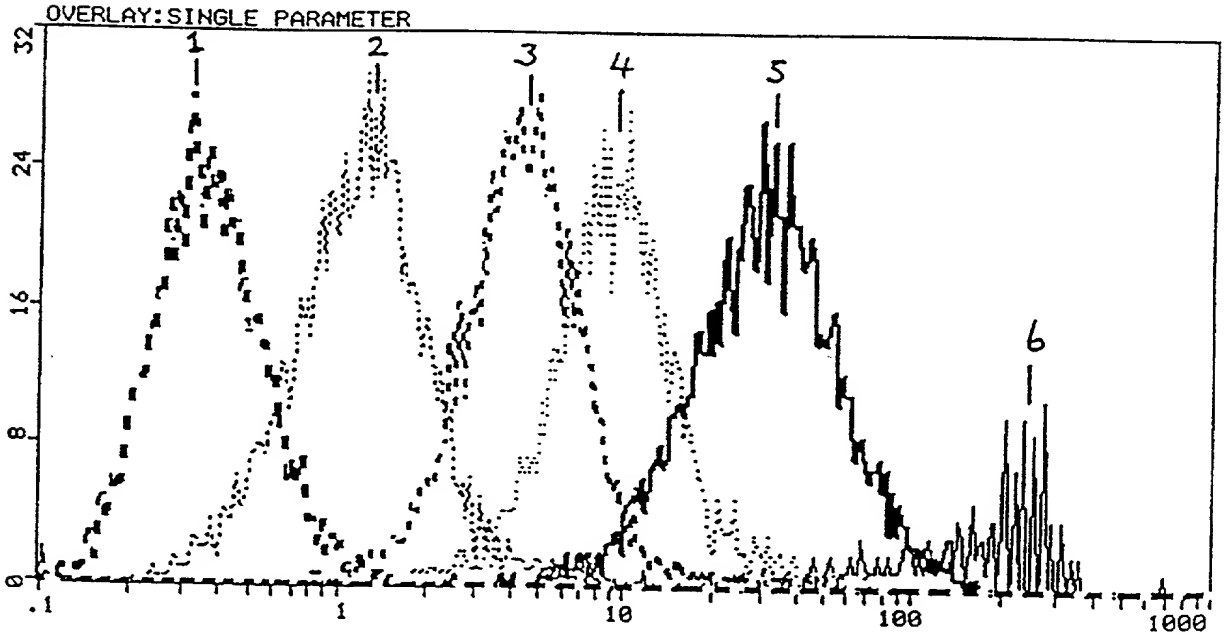

FIGURE 18

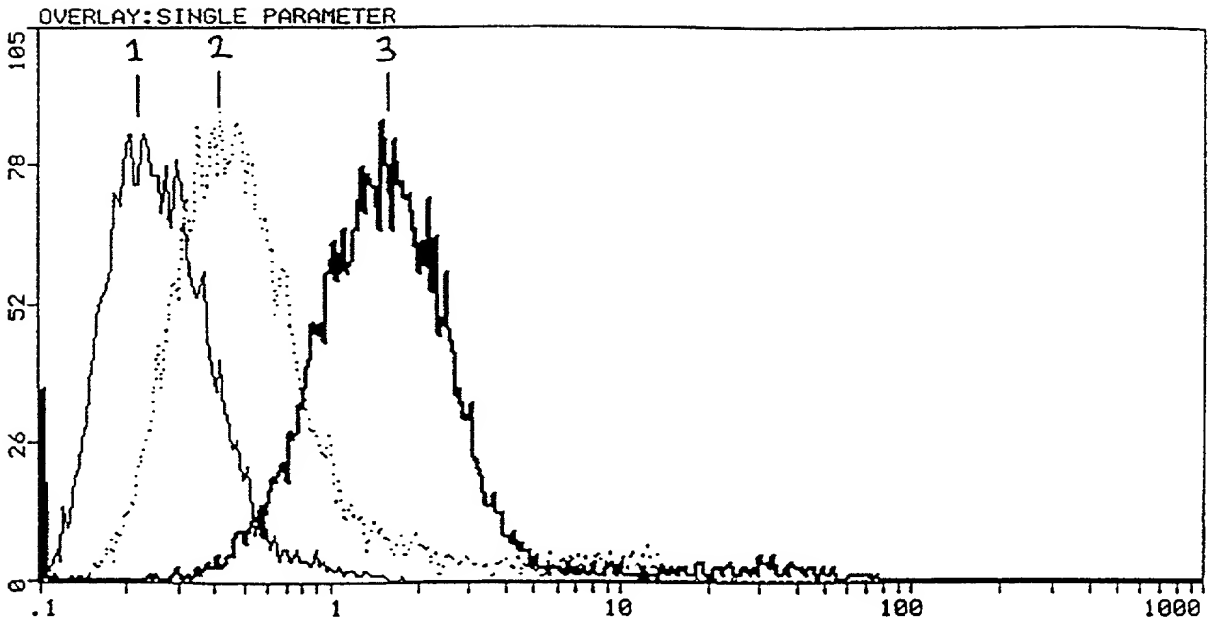

FIGURE 19

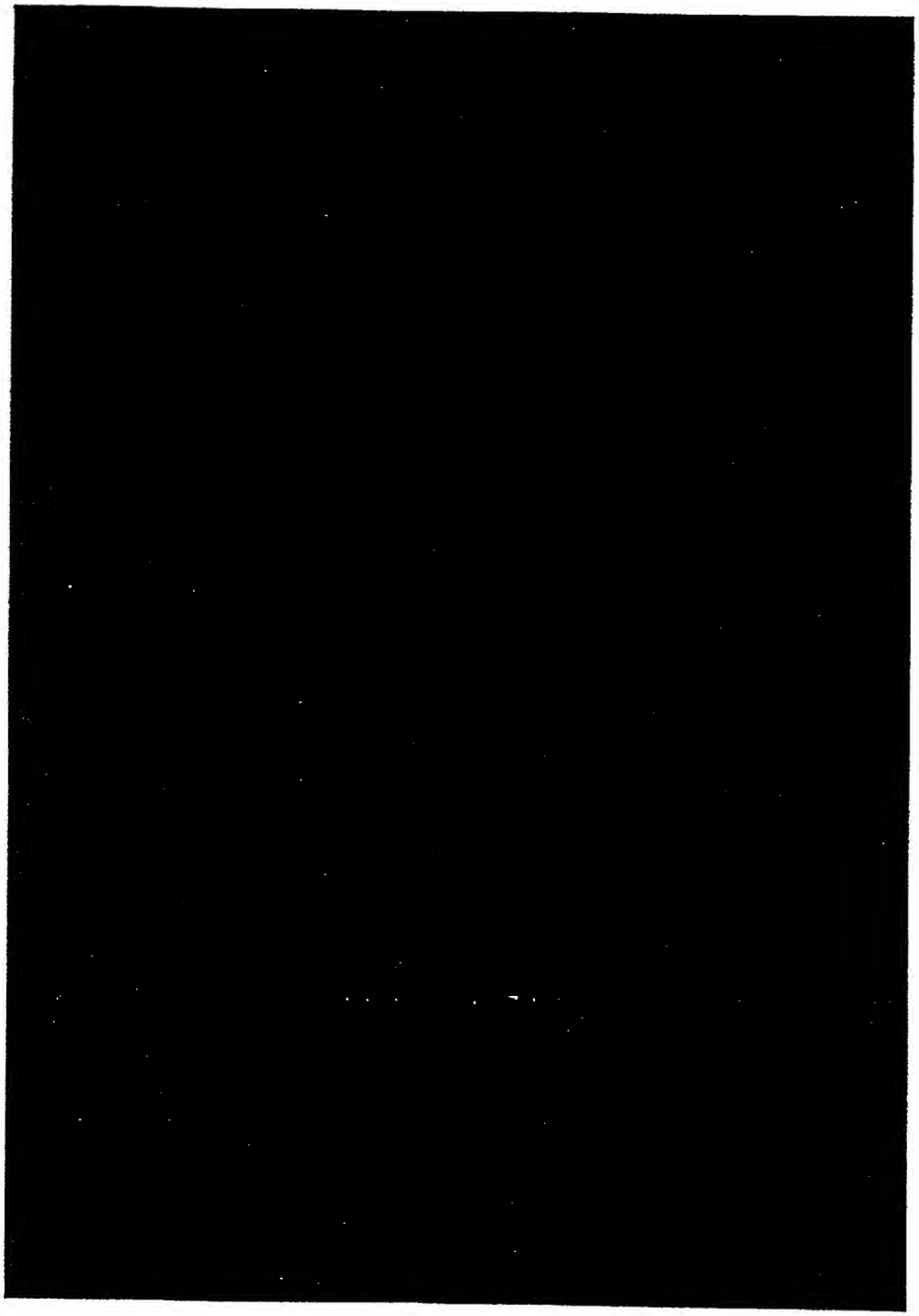

FIGURE 20

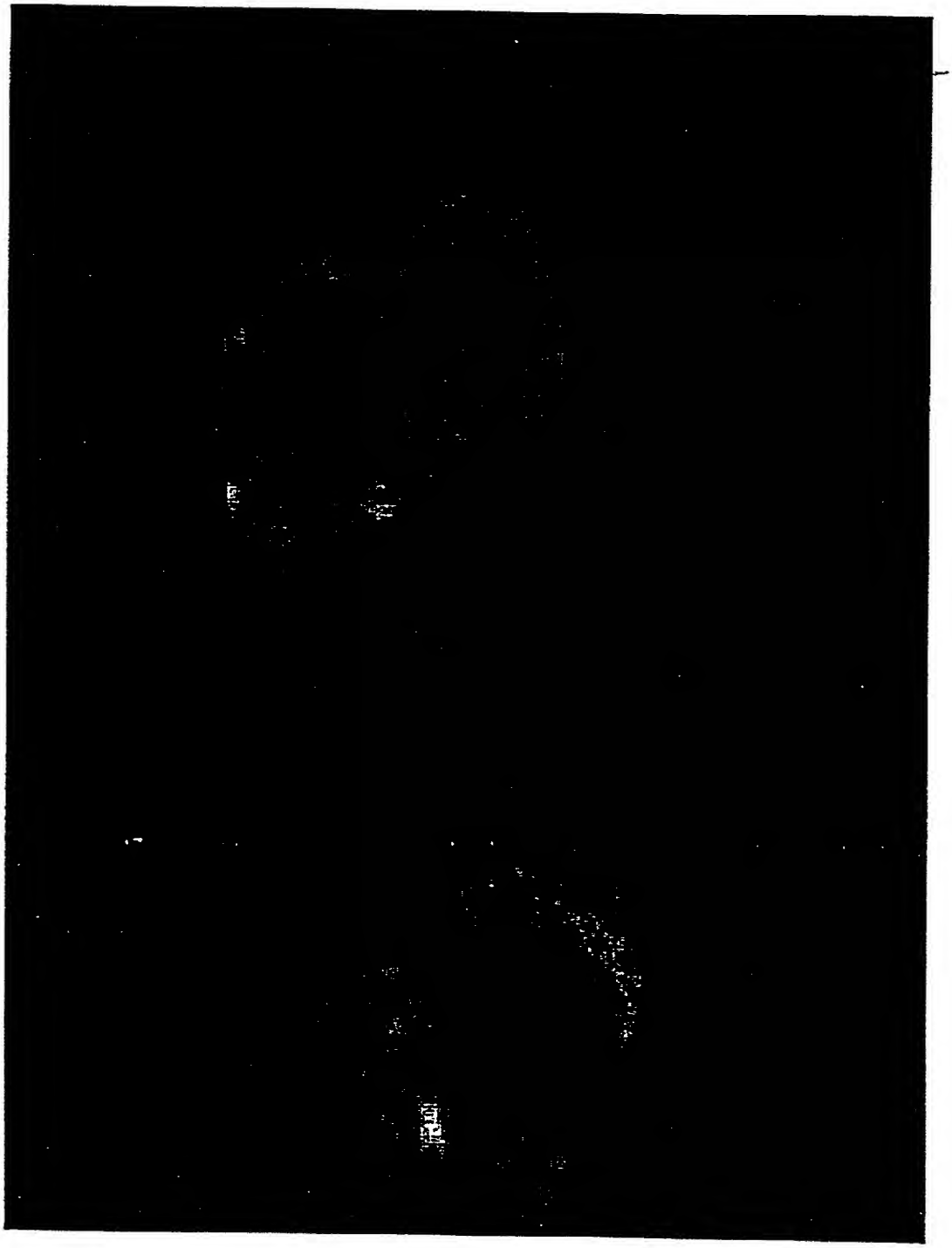

FIGURE 21

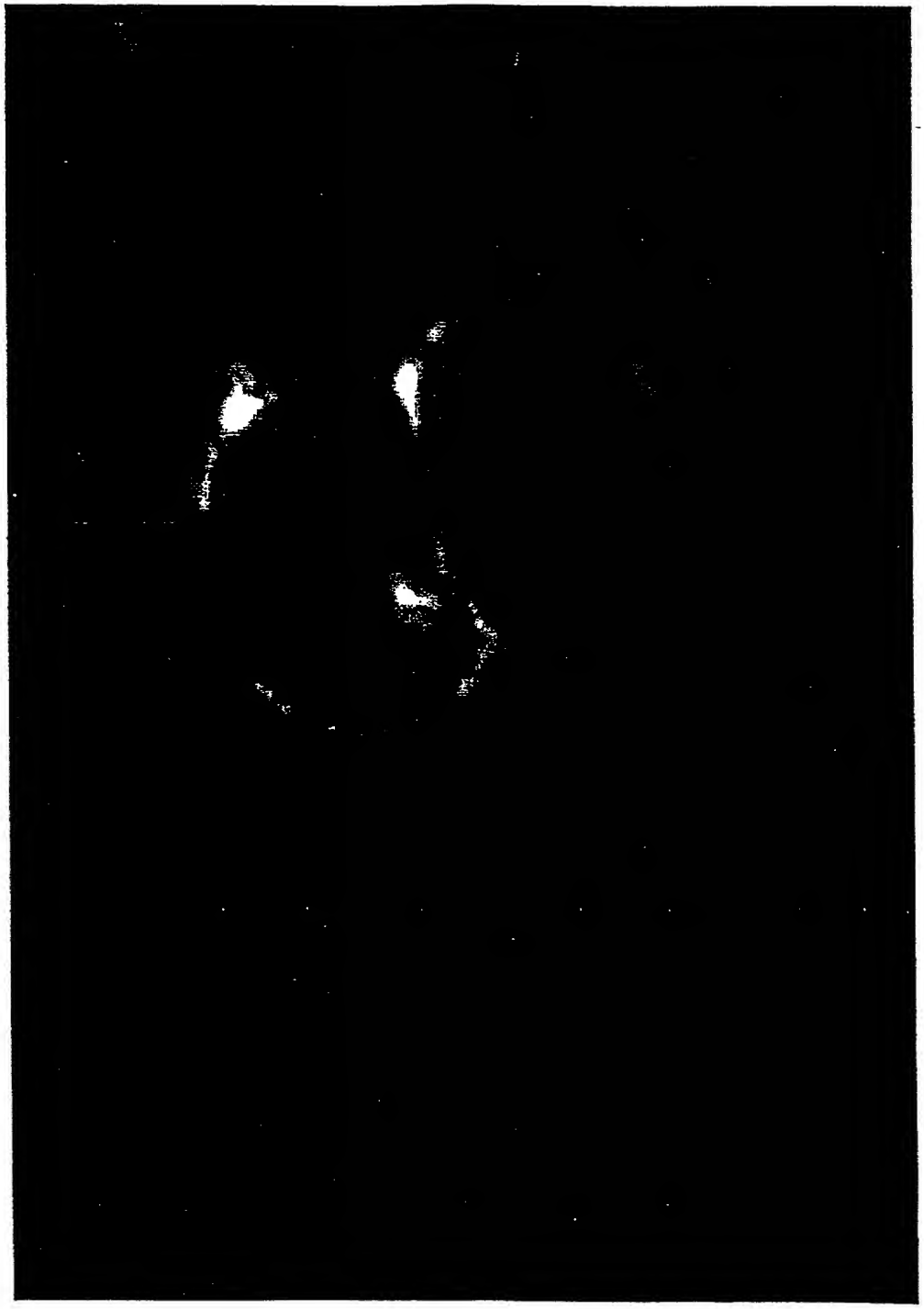

FIGURE 22

PATENT
Docket No.:Griffith

COMBINED DECLARATION AND POWER OF ATTORNEY FOR UTILITY/DESIGN PATENT APPLICATION

AS A BELOW-NAMED INVENTOR, I HEREBY DECLARE THAT:

My residence, citizenship, and post office address are as stated below next to my name.

I believe I am the original, first and sole (or joint, if more than one name appears below) inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

VIRAL PEPTIDES WITH STRUCTURAL HOMOLOGY TO PROTEIN G OF RESPIRATORY SYNCYTIAL VIRUS

the specification of which:

☐ is attached hereto.

☒ was filed on June 4, 1997 as PCT International Application No. PCT/AU97/00351 and was amended on December 4, 1998.

I HAVE REVIEWED AND UNDERSTAND THE CONTENTS OF THE ABOVE-IDENTIFIED SPECIFICATION, INCLUDING THE CLAIMS, AS AMENDED BY ANY AMENDMENT REFERRED TO ABOVE.

I acknowledge and understand that I have a duty to disclose information which is material to the patentability of the claims of this application in accordance with Title 37, Code of Federal Regulations, §§ 1.56(a) and (b).

I hereby claim foreign priority benefits under Title 35, United States Code § 119(a)-(d) of the foreign application(s) for patent indicated below and have also identified below the foreign applications for patent or inventor's certificate on this invention having a filing date before that of the application for patent or inventor's certificate on this invention having a filing date before that of the application on which priority is claimed:

Australia	PO 0265	05/06/96	☒Yes	☐No.
			☐Yes	☐No.
			☐Yes	☐No.
			☐Yes	☐No.
			☐Yes	☐No.

I hereby claim benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

Application Serial No.	Filing Date

I hereby claim benefit under Title 35, United States Code, § 120 of any United States application(s) listed below, and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §§ 1.56(a) and (b) set forth above which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

PCT/AU97/00351	June 4, 1997	☐Patented ☒Pending ☐Abandoned
		☐Patented ☐Pending ☐Abandoned
		☐Patented ☐Pending ☐Abandoned

I hereby appoint the following attorneys and agents to prosecute that application and to transact all business in the Patent and Trademark Office connected therewith and to file, to prosecute and to transact all business in connection with all patent applications directed to the invention:

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Docket No.

pa-324134

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

12/14/98
Date

Signature
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AGK